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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/035,091

12/21/2001

Holly Hogrefe

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AGILENT TECHNOLOGIES INC  
P.O BOX 7599  
BLDG E , LEGAL  
LOVELAND, CO 80537-0599

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

10/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/035,091	<b>Applicant(s)</b> HOGREFE ET AL.	
	<b>Examiner</b> Richard G. Hutson	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,10-12,14,20,22-24,26,30,31 and 33-51 is/are pending in the application.
- 4a) Of the above claim(s) 23,24,26,30,31 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,10-12,14,20,22 and 36-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment of claims 23, 30, 31, 33, 35, in the paper of 6/1/2009, is acknowledged. Claims 1, 3, 10-12, 14, 20, 22, 23, 24, 26, 30, 31, 33-51 are pending and at issue.

Claims 23, 24, 26, 30, 31 and 33-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Upon further consideration it has come to the attention of the examiner that the following rejection should be applied using new art of record. Accordingly this office action is a non-final office action. Any inconvenience to applicant is regretted.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 10-12, 14, 20, 22, 36, 37, 40, 41, 44, 45, 48-51, are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes et al. (U.S. Patent No. 5,436,149), Hogreff (U.S. Patent No. 6,183,997) and Sobek et al. (U.S. Patent No. 6,881,559).

Barnes teach a number of thermostable DNA polymerase mutants and formulations of the taught DNA polymerases and other thermostable DNA polymerases, which formulation of enzymes are capable of efficiently catalyzing the amplification by PCR of unusually long and faithful DNA products. Barnes specifically teach a

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formulation of thermostable DNA polymerases comprising at least one thermostable DNA polymerase lacking 3'-exonuclease activity and at least one thermostable DNA polymerase exhibiting 3'-exonuclease activity, wherein the thermostable DNA polymerase exhibiting 3'-exonuclease activity is a variant of the *Pfu* DNA polymerase wherein the DNA polymerase activity of said *Pfu* DNA polymerase has been diminished or inactivated.

Sobek et al. teach thermostable mutants of B-type DNA polymerases comprising a Y-GG/A amino acid motif between the N-terminal 3'-5'-exonuclease domain and the C-terminal polymerase domain including *Pyrococcus furiosus* DNA polymerase, whereas the tyrosine of the Y-GG/A amino acid motif (i.e. Y385H or Y385N or Y385S) is mutated and whereas these mutant DNA polymerases exhibited improved performance in PCR.

Hogrefe (US Patent No. 6,183,997) teaches compositions of non-naturally occurring mixtures of a polymerase enhancing factor protein and multiple DNA polymerases, including *Pyrococcus* species, JDF3 and KOD DNA polymerases for use in PCR reactions.

One of ordinary skill in the art at the time of filing would have been motivated to use either of the *Pfu* DNA polymerase mutants, Y387H or Y387N or Y387S, taught by Sobek et al. in the formulation taught by Barnes et al. with additional DNA polymerase selected from the group consisting of *Pfu*, JDF3, KOD and Taq DNA polymerases, as taught by Hogrefe, to catalyze the amplification by PCR of unusually long and faithful DNA products. One would have been further motivated to include in the above

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formulation a PCR enhancing factor or an additive, as the purpose of the taught formulation is for PCR and package this formulation as a kit. The motivation for using the *Pfu* DNA polymerase mutants taught by Sobek et al. comes from Barnes who teaches that the thermostable DNA polymerase exhibiting 3'-exonuclease activity of the DNA polymerase formulation is preferably a variant of the *Pfu* DNA polymerase, wherein the DNA polymerase activity of said *Pfu* DNA polymerase has been diminished or inactivated. The mutants taught by Sobek et al. are such variants of the *Pfu* DNA polymerase, wherein the DNA polymerase activity of said *Pfu* DNA polymerase has been diminished or inactivated. The reasonable expectation of success is high as both Barnes and Sobek et al. teach a number of thermostable DNA polymerases for use in the taught formulation, and Sobek et al. specifically teach the *Pfu* DNA polymerase mutants, wherein the DNA polymerase activity of said *Pfu* DNA polymerase has been diminished or inactivated.

Thus claims 1-3, 7, 8, 10-14, 18, 20-22 are made obvious over Barnes et al., Hogrefe and Sobek et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 10-12, 14, 20, 22 and 36-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 2, 5-8, 22, 27, 31, 33, 40-44, of copending Application No. 10/702,400. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed enzyme mixtures of the instant application, comprising a first enzyme and a second enzyme wherein said first enzyme comprises a DNA polymerization activity and said second enzyme is a mutant Pfu DNA polymerase having a mutation at an amino acid position selected from the group consisting of D405, Y410, T542, K593, Y595, Y385, Y387, and G388 and those further limited claims dependent thereon are anticipated by and thus obvious over the corresponding claims of copending Application No. 10/702,400, drawn to a blend of two or more DNA polymerases comprising at least two fusion polypeptide DNA polymerases, each having a proofreading activity wherein one of said polypeptide DNA polymerase has a mutation at an amino acid position of Y387 and those further limited claims dependent thereon.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg  
9/29/2009

/Richard G Hutson/  
Primary Examiner, Art Unit 1652